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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,454	12/05/2006	Riccardo Bertini	4342-0121PUS1	5756

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EXAMINER	
STONE, CHRISTOPHER R	
ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
05/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,454	BERTINI ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed December 4, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 5-14 are pending and under examination. The compound of formula II (claim 10) is the elected specie of compound of formula I currently under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobinick (US 2001/0016195 A1, cited on the IDS filed December 5, 2006) in view of Bertini et al (EP 1123276 B1, provided by Applicant).

Claims 5-14 are drawn to a method of treating spinal cord injury comprising administering the compound of formula II.

Tobinick teaches that antagonists of interleukin-8 (IL-8) are useful in the treatment of spinal cord injury (abstract). Tobinick does not teach the compound of formula II as a particular IL-8 antagonist or the regimen specified by claims 11-13. Bertini et al (EP 1123276 B1, provided by Applicant) teaches that the compound of formula II is an IL-8 antagonist (p. 14, lines 12-27, useful in the treatment of IL-8 mediated pathologies when administered intravenously or intramuscularly, as a bolus, at a daily dosage of from 1 to 1500mg (p. 16, line 23 to p. 17, line 17). Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of the instantly claimed invention to administer the compound of formula II intravenously or intramuscularly, as a bolus, at a daily dosage of from 1 to 1500mg to a patient with a spinal cord injury, since this regimen was known to inhibit IL-8 and IL-8 inhibitors were known to be useful in the treatment of spinal cord injury, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success. Tobinick and Bertini et al do not expressly teach that said method blocks oligodendrocyte apoptosis, reduces tissue damage or promotes recovery following a spinal cord injury; however this language merely states the intended purpose of an active step positively recited, i.e. the administration of the elected specie of compound to a patient with a spinal cord

injury, and thus said language is non-limiting. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of drugs are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims, see Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

Response to Arguments

Applicant alleges that one of ordinary skill in the art would not have a reasonable expectation of success in using an IL-8 inhibitor in the treatment of spinal cord injury (SCI), since the prior art discloses other targets for the treatment of the condition, Tobinick does not correlate IL-8 inhibition with the treatment of SCI, and Tobinick does not provide experimental evidence demonstrating that IL-8 antagonist can be used in the treatment of SCI. This is found unpersuasive because while the art suggests other molecular targets for the treatment of SCI, the art does not discredit the use IL-8 in the treatment of the condition. In fact, Tobinick et al expressly teaches the administration of an IL-8 antagonist for the treatment of SCI and provides a mechanism by which the

compounds act to treat the condition, e.g. anti-inflammatory and neuroprotective activity that ameliorates edema and provides dosing and administration information allowing one of ordinary skill in the art to practice the method with a reasonable expectation of success (see e.g. paragraphs 0067-0068 and claims 24, 25 and 28). With regard to Applicant's characterization of the mechanism of action by which the elected specie of compound treats spinal cord injury (i.e. the finding that the compound blocks oligodendrocyte apoptosis, reduces tissue damage or promotes recovery), it is noted that the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRS

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642